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Department of Veterans Affairs

Clinical Affairs
Medical Service

M–2, Part IV
October 23, 1990

Veterans Health Services and Research Administration
Washington, DC 20420

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Veterans Health Services and
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1. Transmitted is a revision to Veterans Health Services and Research Administration Manual M-2, "Clinical Affairs," Part IV, "Medical Service," chapters 1 through 8. Brackets have not been used to indicate changes.

2. Principal change:

This is a major revision of Part IV, "Medical Service," providing updated and expanded guidance.

3. **Filing Instructions**

Remove pages	**Insert pages**
Cover page through vii	Cover page through iv
1 through 9	1-1 through 8-1
21 through 27	
5-1 through 5-2	

4. **RESCISSION:** M-2, part IV, dated April 15, 1955; and changes 3, 5, 7, 13, 15, and 17. Interim Issue II 10-72-13, dated May 17, 1972.

JAMES W. HOLSINGER, JR., M.D.
Chief Medical Director

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Veterans Health Services and Research Administration Manual M-2, "Clinical Affairs," Part IV, "Medical Service," is published for the compliance of all concerned.

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CHAPTER 1. ADMINISTRATIVE

1.01 MEDICAL OFFICER OF THE DAY

a. The Chief of Staff will develop and issue written guidelines to provide continuous, appropriate and effective medical supervision 24 hours a day, 7 days a week. The guidelines will specify the authorizations, responsibilities, duties, schedules and assignments which are elements of the arrangement.

b. In determining this pattern of medical supervision, due consideration will be given to the type of patients, the number of beds, the number and spatial arrangement of buildings in the hospital complex, and all other factors influencing patient care.

c. One or more duly licensed physicians, with appropriate clinical credentials and privileges, will be assigned to provide medical coverage during evenings, nights, weekends and holidays when the regular medical staff is not on duty. Physicians shall be referred to as AOD (Admitting Officer of the Day), when serving as general practitioners. When more than one physician is scheduled (as at many affiliated medical centers due to the volume or complexity of the patients being covered), specialty and/or subspecialty titles should be used, as in SOD (Surgical Admitting Officer of the Day) or POD (Psychiatry Admitting Officer of the Day). Call schedules need to be clearly posted for use by the triage area, nursing stations and page operators.

d. AODs responsible for performing resuscitations (e.g., no separate code team), will have current ACLS (Advanced Cardiac Life Support) certification.

e. A report either written or oral, will be provided to the designated administrator at the end of each shift.

f. The AODs will not leave the facility grounds during their call shift without the permission of the Chief of Staff, at which time another physician will be designated.

g. The term senior MOD has been occasionally used for a member of the full-time staff on call for administrative issues from home. This is not to be confused with AOD (in-hospital coverage). Similarly, some highly affiliated medical centers employ multiple Officers of the Day, in addition to the admitting teams. Thus terminology must be clearly defined by the Chief of Staff in the guidelines for hospital coverage and must be consistent with JCAHO (Joint Commission on Accreditation of Healthcare Organizations) requirements.

1.02 GENERAL SUPERVISION OF HOUSE OFFICERS

a. House officers training at VA medical centers will be appropriately supervised by attending physicians throughout their rotations. Responsibility for the care of each patient lies with the attending to whom the patient is assigned and who supervises the care rendered by the house staff. All VA patients will have an attending, whose name will be reflected in the patient's medical record. For outpatients, an attending from each clinic will be responsible for the care given in that clinic.

b. A designated attending physician, often the Chief of Service, will serve as the coordinator of residency training activities for that service/section. Responsibilities

include working with the Program Director of the affiliated residency to assure that the rotation is suitable for the house officer's training.

c. Staff attendings are responsible for assuring that procedures performed by house staff are medically indicated and properly supervised and executed. The attending is responsible for diagnostic and therapeutic studies performed, including concurrence with the selection of imaging and laboratory procedures.

d. Written documentation of supervision by the responsible attending will appear in each chart, including concurrence with the stated diagnoses and treatment plans. On consultation rotations, evidence of sub-specialty attending physician involvement should be documented in writing.

e. Residency coordinators, working with Residency Program Directors and attending physicians, will ensure that house officers perform and/or interpret only those critical diagnostic tests and procedures for which they have demonstrated competence.

1.03 CODES

a. Medical Center physicians will ensure swift response times by skilled personnel. All members of code teams must have beepers and will be reached via designated pagers.

b. In order to assure consistent resuscitation procedures, the VA supports the use of the most current ACLS (Advanced Cardiac Life Support) guidelines written and updated by the AHA (American Heart Association). ACLS certification is required to run or supervise any code at a VA medical center. CPR (Cardiac Pulmonary Resuscitation) should be initiated by staff witnessing a code until the code team (ACLS-trained personnel) arrives.

c. **Physicians on the Code Team.** The policies are to become effective within 6 months after receipt by your facility of this revised manual chapter.

(1) **Daytime hospital coverage**

(a) ACLS-certified Chief Resident or Staff physician as supervisor to ensure that the ACLS protocol is correctly applied (some medical centers rely on fellows). Thus a PGY 4 fellow, chief resident, or staff physician is given a code beeper for daytime codes (8:00 a.m. to 4:30 p.m.), and will supervise all daytime codes. This provides for teaching of house officers and uncertified staff physicians, as well as assuring appropriate interventions.

(b) A House officer or full-time staff physician will run the code, but subject to the advice and concurrence of the supervisor. Running the code requires ACLS certification.

(c) A fully trained individual (surgical or anesthesia house officer, fulltime staff, respiratory therapist or nurse anesthetist) will intubate the patient and remain present to assist with any needed IV's.

(d) Additional house officers, students or full-time staff responsible for the patient, will assist in the performance of the code under supervision as above. They are the only physician members of the team who may participate without current ACLS certification.

(2) Night time hospital coverage

Medical team on call will perform off hours codes. Current ACLS certification is required. Non-ACLS certified housestaff will perform only under the direct auspices of the code supervisor.

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CHAPTER 2. CARDIOLOGY

SECTION I. INVASIVE CARDIOVASCULAR SERVICES

2.01 CARDIAC CATHETERIZATION LABORATORIES

a. Invasive cardiovascular procedures will only be performed in appropriately authorized and equipped laboratories, by experienced, credentialled and privileged staff. Individuals must be board certified in internal medicine, cardiovascular diseases or radiology. Trainees must be directly supervised by a fully qualified staff member.

b. Routine cardiac catheterization currently is performed in 72 laboratories. Angioplasty, valvulopasty, pacemaker insertions and electrophysiologic studies and treatments are performed in the cardiac cath lab as well.

c. The cardiac cath laboratories of VA (Department of Veterans Affairs) are governed by regulations with which new staff members may not be familiar. The VA/DOD (Department of Defense) health resources sharing law calls upon VA and DOD to minimize duplication and underuse of health-care resources. The law also provides VA and DOD facilities with authority to enter into agreements to "share" health-care resources. (See M-1, pt. I, ch. 1, sec. XI). In addition, VA and Public Health Service facilities may enter into agreements to "share" health-care resources under the Economy Act. Exemptions may apply for physically remote, and otherwise underserved areas in order to assure equal access to care.

d. Demographic changes have determined where new facilities are opened, with most of the currently approved but not yet built cath labs located in the sunbelt region. Such new labs have been given preference over second angiography suites within a given VA medical center. Most cath lab equipment is replaceable at 8 to 10 years. Once the decision is made to replace equipment, serviceable devices and in some cases, lead-lined rooms, may be retained for electrophysiology or procedure rooms. This permits two rooms, but just one state-of-the-art angiography suite. VA medical centers performing 1,000 total procedures/year could justify two fully equipped new rooms.

e. Trends in average performance over several years are followed to assess compliance with minimum performance requirements. The minimum number of total procedures for a cath lab is 300; the minimum number of left heart procedures is 250. No new labs will be opened unless nearby labs (including all Federal government labs) are performing an average of 500 cases annually.

f. Approximately five clinical FTE (full-time employee) (for example, 1 chief cath lab physician, 2 RNs (Registered Nurse), 2 cath lab technicians) are required to operate a cath lab performing the minimum number of procedures, and the goal of VA is to achieve 500 procedures per year per lab.

g. Opening a Cath Lab. Approval for the concept must be obtained through VHS&RA's (Veterans Health Services and Research Administration's) formal planning process. The VA medical center Director then submits an application to VA Central Office, Medical Service. Entirely new labs will require availability of on-site cardiac surgery.

h. Retaining a Cath Lab. Once established, a lab will stay open as long as it conforms to the minimum performance requirements of VA and other guidelines which VA accepts. For persistently borderline performance, (in terms of numbers or morbidity and

mortality status) a Central Office site visit team will be sent to evaluate, prior to authorization of new equipment.

i. Closing a Cath Lab. Established criteria are used to determine that a lab should be closed. Failure to achieve a minimal performance standard or to report required statistics may result in closure. Failure to retain or recruit appropriately trained and credentialled staff, unduly high morbidity or a change in the goals of a VA medical center, may result in closure. The stages of closure begin with warning letters, then progress to site visits and formal recommendations through channels. Labs may be phased out through not replacing their equipment (see subpar. d.). Closure of a cath lab is coordinated with other Federal agencies to maintain equitable access to care.

j. Incident Reports. Complications of invasive cardiovascular procedures will be reported quarterly, via AMIS, Section J, or its replacement. All deaths and serious or unusual complications will be reported to VA Central Office, Medical Inspector (19/141A1) by means of VA Form 10-2633, Report of Special Incident Involving a Beneficiary, or its replacement, with a copy kept on file at the cath lab (for 3 years). A cath lab report form for the individual patient must be attached to the incident report form.

(1) Complications must be reported if they occur within 24 hours of the cardiac catheterization or if they are attributable to the catheterization even if remote in time. EXAMPLE: A patient who undergoes an angioplasty and has complications including dissection, myocardial infarction and subsequent renal failure. After a prolonged ICU (Intensive Care Unit) course including hemodialysis, the patient dies.. The death is to be listed as an angioplasty related death (complication of procedure). All episodes of surgery that the patient would not have had if the catheterization had not been performed are also listed as complications.

(2) Given the overall volume of VA cath labs, all unusual complications should be reported to identify trends that may not be detectable at individual facilities. The following list is the minimum for reporting. Other serious complications, (especially those discussed in a staff review or morbidity and mortality conference) should also be included:

(a) Death during or related to catheterization.

(b) Dissection.

(c) Transient ischemic attacks/stroke/paralysis/visual changes.

(d) Myocardial infarction or pulmonary edema within 24-hours of cath.

(e) Renal failure (contrast nephrotoxicity).

(f) Perforation/Tamponade/Rupture.

(g) Amputation/Peripheral Vascular Surgery.

(h) Anaphylaxis.

(i) Pseudoaneurysm/Significant Hematoma/Fistula.

(j) Hypotension, during and after procedure, requiring intra-aortic balloon pump or sustained therapy.

(k) Infection or inflammation: local, requiring drainage.

(l) Septicemia; bacterial endocarditis; thrombophlebitis, requiring more than 7 days of treatment.

(m) Catheter problems: breakage, knotting, balloon rupture.

(n) Bleeding: requiring transfusion or surgery.

(o) Atrial fibrillation/ventricular tachycardia

(p) Ventricular fibrillation/complete heart block

2.02 CORONARY ANGIOPLASTY

a. VA authorizes the use of PTCA (percutaneous transluminal coronary angioplasty) as an elective and emergent procedure in accord with these regulations.

b. Only VA medical centers with on-site cardiac surgery programs are eligible to perform elective angioplasty. Due to the nature of VA which includes in-house programs, contracts and sharing agreements to provide cardiac surgery, VA recognizes circumstances that may merit an exemption. **Formal application for an exemption must be made to VA Central Office Medical Service (13__/141A1).**

c. Requirements for Training. Many VA cardiologists perform invasive procedures at other institutions. VA requires only that the total number of cases for an individual angioplasty attending comply with nationally accepted guidelines. VA medical centers with insufficient volume to achieve such a total experience for the individual angioplasty operator should discontinue performing PTCA, unless an experienced angioplasty attending will directly back-up each case (e.g., a fully-qualified university or community affiliated attending, who is present in the cath lab).

d. Case Reporting. Case reporting is currently through the quarterly AMIS Segment 8JA2. Patients with morbidity or mortality within 24-hours of PTCA, and thereby *including those patients referred urgently to surgery* or sustaining complications in the Cardiac Cath Unit, will also be reported via VA Form 10-2633 (see par. 2.01j). Any cardiology section or affiliated medical school review should be attached, and a copy kept in the cath lab for 3 years. Failure to report could result in laboratory closure.

2.03 PACEMAKERS/IMPLANTABLE DEFIBRILLATORS

a. Veterans with pacemakers and other implantable devices are registered via the National Pacemaker Registry at VA Medical Center, Washington, DC. Currently about 3,000 permanent pacemakers are annually implanted by 102 VA medical centers. VA medical centers must implant about 15 pacemakers per year to remain listed (sufficient volume to keep current). Patients are followed locally for clinical care and reprogramming, and by telephone for routine surveillance. Patients with AICDs (Automatic Implantable Cardioverter Defibrillators) are also followed by about 30 VA medical centers.

b. **Pacemaker Selection**

(1) Shipping/Returns/Explants. Procurement is through the Marketing Center and pacemakers appear on the Federal Supply Schedule. Receipt of a pacemaker is via the

Division of Acquisition and Materiel Management, which maintains a record for pacemaker purchases and returns. Unused pacemakers will be exchanged for credit as authorized, and then deleted from the facility's inventory. Explanted pacemakers, which are removed because of evidence of unexplained clinical failure or because of a FDA (Food and Drug Administration) recall, will be sent by the Chief, Acquisition and Materiel Management Service of VA medical centers to the Eastern Cardiac Pacemaker Surveillance Center, VA Medical Center, 50 Irving Street, NW, Washington, DC, 20422. The explanted pacemaker should be accompanied by a completed VA Form 10-0049. A shipping label and a request for reimbursement by the manufacturer must be provided.

(a) Explanted pacemakers removed due to replacement or cremation can be tested locally and returned to the manufacturer for credit or sent in accordance with subparagraph b(1). If an individual medical center lacks the capability to evaluate an explanted model, it should be returned as stated in subparagraph b(1).

(b) All VA medical centers need to ensure that credit is sought for explanted/pacemakers still under warranty. If sent to the Eastern Pacemaker Surveillance Center, they will use the mailing label provided and including the request for reimbursement. A report on the operating characteristics of the explanted pacemaker will be sent to the originating VA medical center, to the manufacturer and to the FDA. If evaluated at the individual medical center, the pacemaker should be returned directly to the manufacturer for possible credit. All generators should be non-invasively analyzed such that VA can obtain credits toward new devices.

(2) Cremation. When an autopsy is performed, Standard Form 523, Authorization for Autopsy, will document the removal of the pacemaker. Otherwise, the Chief of Pathology or designee shall seek authorization (documented on Standard Form 507, Clinical Record Report) from the family to remove the pulse generator. If the pulse generator is not removed from the body, the Death Certificate must clearly state its presence. For example: **NOTE:** *BODY CONTAINS A PACEMAKER WHICH INCLUDES A BATTERY OR POWER SOURCE.* Pathology should dispose of generators as described.

(3) Administrative Registry. Discontinued. Clinical, see subparagraph c(1) and (2).

(4) Other Equipment. Veterans electing pacemaker follow-up through VA will be supplied with attachments necessary for telephone surveillance. VA medical centers may not use any free monitoring services offered by vendors or manufacturers directly or indirectly (does not apply to loaned programmer equipment).

c. There are two pacemaker surveillance centers for telephone monitoring:

(1) The Eastern Pacemaker Surveillance Center, VA Medical Center, Washington, DC, serves pacemaker recipients East of the Mississippi River. It is the location of the National Pacemaker Registry and will analyze explanted cardiac pacemakers. For clinical issues call: FTS 921-8398 or 1-800-543-PACE (7223).

(2) The Western Pacemaker Surveillance Center, VA Medical Center, San Francisco, CA, serves pacemaker recipients West of the Mississippi River. For clinical issues call FTS 470-2079.

d. The Surveillance Centers can save time and effort for VA medical centers, as well as provide pacemaker expertise to remote/underserved areas on a device-specific basis.

The VA medical center where the implant is performed or where the patient is followed, is responsible for making sure that stable pacing parameters are achieved. Telephone surveillance decreases clinic appointments. Most VA medical centers now defer telephone monitoring to the surveillance centers, which provide computerized reports back to the clinicians. Clinical follow-up is provided at VA medical centers or via fee-basis if not otherwise available locally.

e. All veterans with pacemakers will continue to be offered telephone surveillance, either from an individual VA medical center or one of the two (Eastern or Western) pacemaker surveillance centers, even if they are no longer followed in a VA clinic. VA medical centers discharging patients from their clinics, or discontinuing clinics, must ensure that all pacemaker patients continue to be offered telephone surveillance. Any alternative method (to follow-up by one of the pacemaker surveillance centers) requires specific approval, with individual requests directed to 13_/141A1.

f. PRCs (Pacemaker Referral Centers) *AICD Implant Center

PRCs

Boston, MA
Providence, RI
West Roxbury, MA
White River Junction, VT

Albany, NY
Buffalo, NY
Syracuse, NY

Bronx, NY
Brooklyn, NY
New York, NY
Northport, NY
San Juan, PR
*West Haven, CT

East Orange, NJ
Philadelphia, PA
Wilkes-Barre, PA
Wilmington, DE

Clarksburg, WV
Pittsburgh (Univ. Drive), PA

Baltimore, MD
*Washington, DC

Hampton, VA
Huntington, WV
*Richmond, VA
Salem, VA

Asheville, NC
Durham, NC
Mountain Home, TN

Atlanta (Decatur), GA
*Augusta, GA
*Charleston, SC
Columbia, SC

Biloxi, MS
Birmingham, AL
Jackson, MS
Tuskegee, AL

*Lexington, KY
Louisville, KY
Memphis, TN
*Nashville, TN

Bay Pines, FL
*Gainesville, FL
*Miami, FL
*Tampa, FL

Cincinnati, OH
Cleveland, OH
Dayton, OH

Allen Park, MI
*Ann Arbor, MI

Fort Wayne, IN
*Indianapolis, IN
Marion, IL

Madison, WI
*Milwaukee (Wood), WI

*Columbia, MO
Kansas City, MO
Topeka, KS
Wichita, KS

Chicago (Lakeside), IL
Chicago (West Side), IL
North Chicago, IL
*Hines, IL

Fargo, ND
*Minneapolis, MN
Sioux Falls, SD

Des Moines, IA
Iowa City, IA
Lincoln, NE
Omaha, NE

Denver, CO
Ft. Meade, SD
*Salt Lake City, UT

Loma Linda, CA
Long Beach, CA
*West Los Angeles, CA

San Diego, CA
Sepulveda, CA

Fresno, CA
Livermore, CA
Martinez, CA
Palo Alto, CA
Reno, NV
*San Francisco, CA

Boise, ID
Portland, OR
Seattle, WA
Spokane, WA

*Little Rock, AR
Muskogee, OK
New Orleans, LA
*Oklahoma City, OK
Shreveport, LA
St. Louis, MO
*Dallas, TX
Houston, TX
*San Antonio, TX
Temple, TX

*Albuquerque, NM
Amarillo, TX
Phoenix, AZ
*Tucson, AZ

SECTION II. NON-INVASIVE CARDIOVASCULAR SERVICES

2.04 NON-INVASIVE MODALITIES

a. Computerization has improved accessibility of ECG (Electrocardiograph) records for patient care and VA has a systemwide interest in completing the computerization of ECG records. Before any large ECG storage system is purchased, the VA medical center should discuss equipment with its nearby referral medical centers, as well as any DOD hospitals or clinics with whom they actively share cardiac services, to discuss compatibility. Without written sharing agreements in effect, compatibility is not an issue for purchasing this equipment.

b. VA medical centers in remote or underserved areas now have access to the skills of cardiologists at tertiary care centers, who can remotely edit and interpret their records, and return them to the medical center of origin over FTS lines.

c. AMIS reporting of numbers of ECG and stress tests is no longer required.

d. Prior to purchasing any Holter equipment, a VA medical center should discuss acquisition with its nearby referring VA and DOD medical centers as well as hospitals with which it has sharing agreements. This technology will permit greater networking between VA medical centers in the future.

e. The authority to contract for up to 5 years to acquire supplies and services for use in VA facilities when determined in VA's best interest may make maintaining up-to-date echo equipment easier. See VA Acquisition Regulation 817.102-1. Most VA medical centers have Doppler, 2D and M-mode echo. Many tertiary and some secondary care medical centers have continuous wave and color Doppler. The addition of such modalities as stress, transesophageal, intraoperative and peripheral vascular ultrasound requires collaborating purchases with surgery and radiology, as well as referring medical centers.

f. As signs are replaced, the terms phonocardiography and vector-cardiography and "Eidetics" may be eliminated.

g. Non-nuclear stress test facilities can sometimes be used for cardiac rehabilitation as well. Many rooms formerly designated "Eidetics," under recent space-planning criteria, should be spacious enough to permit cardiac rehabilitation programs. In some medical centers, stress testing is performed in the morning and cardiac rehabilitation in the afternoon. Busy tertiary care hospitals may require two rooms.

h. Complications in the stress lab should be reported by means of a VA Form 10-2633, (see para. 2.01j) to include:

(1) Death during or after treadmill test.

(2) Asystole.

(3) Permanent injury (i.e., resulting in permanent disability).

(4) Myocardial Infarction.

(5) Ventricular tachycardia.

(6) Ventricular fibrillation.

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CHAPTER 3. SPECIALIZED MEDICAL PROGRAMS

3.01 ICUs (INTENSIVE CARE UNITS)

a. VA medical centers with ICUs must provide certain minimal services. Not all medical centers have ICUs. Depending on the patient population served by a given facility, critical care may be provided on-site, by transfer to another VA medical center, or by fee-basis or sharing agreement. In all cases, the object is to provide the best possible critical care for the individual patient.

b. Each ICU will have a designated physician chief who is a member of the VA staff with appropriate Board certification and clinical privileges. The ICU Chief is administratively responsible for all aspects of the care given in the ICU around the clock, and has an office near the ICU. At times when the ICU Chief is not available (e.g., sick or annual leave, national meetings or conferences), a qualified physician will be designated to act for the ICU Chief.

c. The ICU Chief is responsible for directing all aspects of the operation of the unit, as well as for developing operating policies including admission criteria. The ICU Chief will be assisted by a multidisciplinary ICU committee that meets at least quarterly. This committee is composed of representatives from all subspecialties involved in critical care.

d. Only licensed physicians will function independently in ICUs. Physicians-in-training must be directly supervised by qualified, licensed physicians (e.g., PGY 2 or above) for all procedures. Physician assistants and CRNA's will act only in accord with physician orders and specific clinical privileges. Doctors working with intensive care patients must have individual beepers. Only appropriately trained physicians will perform invasive procedures in intensive care units. *Note that this includes central venous access and arterial cannulations in all forms.*

e. Each ICU must have fully qualified critical care nurses to provide nursing care. At least one ICU nurse per shift must be fully trained in cardiac output determinations, and privileged to perform same if the ICU has capability for Swan-Ganz monitoring. In tertiary care centers, at least one nurse per shift must be privileged to care for patients with temporary transvenous pacemakers and intra-aortic balloon pumps if these modalities are within the unit's capabilities. Lack of such staff is a sufficient reason to transfer a critically ill patient to another facility.

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CHAPTER 4. DIALYSIS PROGRAM

SECTION I. GENERAL

4.01 POLICY

VA (Department of Veterans Affairs) will appropriately treat patients with ESRD (end stage renal disease) as indicated by competent professional judgment. This may include conservative therapy, hemodialysis and peritoneal dialysis in a medical facility or at home, and renal transplantation. The extensive professional expertise and other resources necessary to provide proper ESRD care require that designated dialysis units be located and operated for maximum effectiveness and efficiency. Only VA facilities having the approval of the appropriate Regional Director with concurrence of VA Central Office Medical Service should undertake chronic dialysis care. However, no VA medical center with the necessary expertise is barred from performing acute dialysis when medically necessary. This chapter contains policy and guidelines for operation of the VA dialysis units.

4.02 ELIGIBILITY FOR CARE--GENERAL CONSIDERATIONS

a. Priorities for treatment of patients will conform to established beneficiary priorities for VA hospital care and outpatient care.

b. Within beneficiary priority classes highest priority for dialysis treatment will be given to seriously ill or unstable patients urgently in need of care and lowest priority will be given to clinically stable patients receiving ESRD care in a non-VA program who seek elective transfer into a VA program. Veterans who are NSC (nonservice-connected) for renal disease and who are stable and receiving care in a non-VA program may be accepted for transfer into a VA dialysis unit on a space-available basis in accordance with pertinent eligibility regulations. Such NSC patients seeking VA care should be informed by the dialysis and/or medical administrative staff that the VA ordinarily will not pay for subsequent care in a non-VA unit (such as if they live too far from a VA medical center having a dialysis program if the VA dialysis program becomes overtaxed) unless the patient's other resources, such as Medicare, are clearly inadequate to support such treatments. Veterans shall not be admitted for the sole purpose of placing them on OPT-NSC (outpatient nonservice-connected) care. (See par. 4.06 for further information on VA support of patients in non-VA dialysis units.) When a veteran patient is denied acceptance into a VA dialysis program because of lack of capability, the VA staff should assist the patient in identifying an alternate source or sources of dialysis treatment.

4.03 PROGRAM COMPONENTS

a. Dialysis Center. A VA medical center designated as a dialysis center is capable of providing the full spectrum of dialysis related diagnostic and therapeutic services required by patients with end stage renal disease. Each VA dialysis center will have appropriate arrangements for evaluating patients as transplantation candidates and for appropriate referral for transplantation. Transplantation may be performed either within the VA medical center, at another VA medical center or in a non-VA facility depending on local circumstances (e.g., available resources, sharing agreements, patient preference and other eligibilities such as Medicare, etc.). See M-2, part XIV, chapter 7, regarding VA transplantation programs.

b. VA Satellite Dialysis Unit. A Satellite Dialysis Unit is a designated program in a VA medical center initially intended to provide continued dialysis treatment to stable ESRD patients. The exact responsibilities carried out by a Satellite Dialysis Unit will depend upon the local needs and the resources at the Satellite as outlined in a formal written affiliation agreement with an affiliated VA dialysis center. Some Satellite Dialysis Units with the necessary expertise have been authorized to function independently as Interim Dialysis Centers.

SECTION II. DIALYSIS CARE PROVIDED BY VA MEDICAL CENTERS

4.04 SCOPE OF VA DIALYSIS PROGRAM ACTIVITIES AND ADMINISTRATIVE CONSIDERATIONS

a. Diagnostic Study, Initial Stabilization and Formulation of Treatment Plan, Periodic Review and Reevaluation of Therapy. Dialysis center staff will ordinarily carry out these activities which require multidisciplinary professional expertise.

b. Maintenance Assisted (Full-Care) Dialysis. Patients who are not suitable for home dialysis or limited/self-care dialysis may require continued assisted full-care dialysis either at a dialysis center or satellite. Decisions on mode and location of dialysis treatment will be made by the dialysis center staff.

c. Home Dialysis. Suitable patients and their assistants may be trained to perform dialysis at home. VA encourages home dialysis which permits dialysis facilities to treat additional patients, may offer potential rehabilitation benefits to the patient, and is less costly than continued dialysis in a medical center. Therefore, all VA dialysis centers will also provide home/self dialysis training so that selected patients can continue their dialysis treatments at home, or perform limited/self-care dialysis at dialysis centers or satellites if home dialysis is not feasible. Selection of home dialysis treatment is based on professional determinations of patient suitability by the dialysis program staff and consent of the patient. In home dialysis, VA will provide support services, including supplies and ongoing technical and professional assistance in addition to placement and installation of dialysis equipment in the patient's home. Home dialysis equipment will be provided only after there is assurance that the dialysis patient and the attendant are adequately trained, and trained VA personnel are available to provide backup consultation and assistance.

d. Home Dialysis Attendants. VA will provide instruction, and may provide financial support for home dialysis attendants during the instruction period. Such support can be provided either by appointment of the attendant as a "without compensation employee" for the training period, with payment for travel and per diem during the training period, or by use of a contract with the person to be trained. VA does not encourage the use of paid home dialysis attendants in lieu of family members. However, under extraordinary circumstances, such as when a family member is not available to assist with dialysis care, use of such an attendant may be the most satisfactory alternative for the patient and preferable to other alternatives from a cost/effectiveness standpoint. In such cases, VA will continue to exercise overall professional responsibility for the patient's care, including assessing the performance capability of the proposed attendant and periodically monitoring and evaluating the actual performance of the home dialysis attendant. VA patient and potential dialysis attendant should be informed that VA does not assume responsibility for the performance of the dialysis attendant or for any untoward effect

(such as hepatitis) that the attendants may develop. The use of a formal agreement for the functioning of the dialysis attendant would be most helpful, and is encouraged. The patient and VA-trained attendant might properly be parties to such agreement, which should include provision for listing the risks to the patient entailed in dialysis, the responsibilities of the attendant, and the fact that the attendant is not considered to function as an employee of VA. The Office of District Counsel is available to assist in drafting such agreements. Dialysis attendants may be recruited directly by the patient, with assistance of the Dialysis Unit, or existing community resources may be utilized.

e. Limited/Self-Care Dialysis. Selected patients for whom home dialysis is not feasible may be trained to participate actively, to the extent possible, in dialysis treatment provided at a dialysis facility. Thus, only the minimum amount of staff assistance will be necessary. VA encourages such limited/self-care dialysis where appropriate, and additional resources in support of such activities have been provided to many dialysis programs. It has been found that limited/self-care dialysis programs are more successful if such activities are carried out separately from the assisted full-care dialysis treatment.

f. Contract and Fee-Basis Dialysis. See paragraph 4.06.

4.05 GUIDELINES FOR VA DIALYSIS UNIT OPERATION

a. Introduction. Operation of a dialysis program requires consideration of various distinct functions including:

(1) Formulation and modification of basic policies and procedures,

(2) Ongoing clinical decision making, and

(3) Conducting quality assurance studies.

These functions must be distinguished since the necessary participants and their roles vary.

b. ESRD (End Stage Renal Disease) Committee

(1) A medical center ESRD Committee will be established in each dialysis center to formulate basic policies and procedures, accept patients into the renal replacement program and oversee program activities. The Chief of the Renal Section of the Medical Service and the Chief of the Transplant section of the Surgical Service will serve on this committee and jointly recommend appointment of the members. Either the Chief of the Renal Section or Transplant Section may serve as chairperson. In hospitals where only dialysis facilities exist, the Chief of the Renal Section of the Medical Service will serve as chairperson of the committee and recommend appointment of the other members. The surgeon responsible for surgical problems of ESRD patients will be a member. Since multidisciplinary professional expertise must be available to implement proper ESRD policies, the function for satellite units will ordinarily be carried out at the parent center. At least three physicians will serve on the ESRD Committee, one of whom will serve as chairperson. Non-physician participants including a nephrology nurse, nephrology social worker and dietitian will be appointed to the committee. If the above requirements are met, existing dialysis and transplant committees whether in combination with a university committee or existing totally within VA may be

used. The medical center Director will establish the ESRD Committee and approve its membership.

(2) The ESRD Committee will formulate basic policies and procedures for the dialysis program, approve the program's policy and procedure manual, accept patients into the renal replacement program, and periodically review clinical care, outcome of therapy, and complications. The likely quality of life and outcome of dialysis therapy should be considered when formulating medical admission criteria. Each patient will be considered on an individual basis and no patient should be excluded from the consideration process solely because of a specific diagnosis. The committee will take such actions as are appropriate and/or offer its recommendations to the medical center Director through the Clinical Executive Board to improve ESRD patient care. The ESRD Committee minutes will include a listing of individuals attending and actions taken.

c. Policy and Procedure Manual. Each Dialysis Unit will develop and maintain a manual approved by the ESRD Committee outlining operational objectives, basic policies and approved procedures adopted to assure a high level of patient care. National guidelines/standards developed by recognized agencies/organizations such as AAMI (Association for the Advancement of Medical Instrumentation), CDC, FDA, OSHA, Surgeon General and JCAHO should be considered and incorporated as appropriate. Areas covered will include the following:

(1) Admission criteria and procedures to ensure equitable access to ESRD care in accordance with general VA policies and priorities.

(2) Staffing policies for physician and nonphysician personnel in cooperation with other involved services, such a Nursing, Social Work and Dietetics.

(3) Procedures for assuring health and safety of patients and staff including:

(a) Hepatitis and other infectious disease control, including information, instructions and precautions for home dialysis patients and attendants.

(b) Air embolism prevention and treatment.

(c) Policy and procedures for dialyzer use (including reuse if any).

(d) Standards for dialysate composition, conductivity and temperature.

(e) Water purification standards and testing requirements.

(f) Blood leak detection and control.

(g) Use of monitoring devices, alarms, and other safeguards.

(h) Provisions for emergency medical care.

(i) Provisions for power failure, fire, and other nonmedical emergencies.

(j) Provisions of social services to help maintain normal social functioning of the patient and the family.

(4) Procedures for ongoing monitoring and modifying of individual short- and long-term patient care plans including dialysis treatments, medications, diet, suitability for transplant, psychosocial evaluations, special treatment and continuing care. Such ongoing decision-making will include input from the various professionals involved in the care of the individual patients.

(5) Patient rights, including right to privacy and confidentiality, right to information about medical condition and treatment, and right to participate in selection of treatment options.

(6) Relationship to other VA or non-VA dialysis or transplant facilities including affiliated VA satellite unit or center, if any, and to community ESRD organizations.

d. QA (Quality Assurance). QA activities relating to ESRD care including medical audit and utilization review will be integrated into the hospital's overall QA program. Recommended elements for dialysis-specific QA include the following: qualified physician director; functioning ESRD committee; written plan including policy and procedure manual; monitoring use of safeguards, alarms, monitors and procedures (e.g., relating to water quality, dialysis equipment and supplies, dialyzer reuse and including home dialysis patients) for conformance to national guidelines; review of all deaths and serious complications relating to dialysis; periodic review of patient data for maintenance of pre-set targets for clinical, hematological and blood chemistry values; participation in local ESRD network (strongly encouraged by the VA Ad Hoc Advisory Group on Renal Disease and Dialysis); periodic review of mortality statistics and comparison to national data and periodically review experience relating to staff physician supervision of residents and non-physician staff, vascular access, infections, rehospitalization, use of consultations, patient complaints, litigation, etc., which may reflect on quality of care. Results of ESRD QA studies will be reviewed by the medical center ESRD Committee and appropriate actions undertaken or recommended.

e. Relations of VA ESRD Programs to Community ESRD Organizations and local ESRD Networks

(1) VA data for the USRDS (US Renal Data System) will be submitted through the local ESRD "Network" (see par. 4.08b).

(2) VA medical centers which provide ESRD care to non-VA patients through sharing agreements and which have been authorized by agreement between VA and the Department of Health and Human Services and approved as a Medicare ESRD provider will be accorded full membership rights in the local ESRD "network" and will conform to the Medicare Patient Information System, Medical Review Boards, and other requirements with regard to Medicare (but not VA) patient care. In addition, aggregate VA data will be provided and both VA and non-VA patients use will be included in calculating utilization rates. VA patient data identified by individual and care provided to individual VA patients will not be subject to any mandatory review or external control. Release of patient data will be in accordance with established policies and procedures governing disclosure of medical information, based upon the Privacy Act of 1974 (5 U.S.C. 5552a) and VA confidentiality status (38 U.S.C. 3301 and 4132). (See subpar. (4) below for clarification of the terms "patient data" and "aggregate VA data.")

(3) VA medical centers where Medicare patients are not treated, are encouraged to participate voluntarily in local network activities, to the extent possible, in the interest

of improved patient care. As with those VA facilities that do treat Medicare patients, aggregate VA data may be provided but patient data identified by individual and care provided to individual VA patients will not be subject to any mandatory review or external control. Release of patient data will be in accordance with established policies and procedures governing disclosures of medical information, based upon the Privacy Act of 1974 (5 U.S.C 5552a) and VA confidentiality status (38 U.S.C. 3301 and 4132). (See subpar. (4) for clarification of the terms "patient data" and "aggregate VA data.")

(4) VA employees designated to serve in network activities should avoid participation that would conflict with, or give the appearance of conflicting with, their duties as VA employees. VA Standards of Ethical Conduct and Related Responsibilities, set forth in pertinent part in VA Regulations 800 through 823, should serve as guidelines. Further guidance may be sought from one's District Counsel.

(5) In this subparagraph the term "patient data" refers to individually identifiable information while the term "aggregate VA data" refers to statistical, nonindividually identifiable information.

f. VA support of Dialysis Care in Non-VA Facilities. See paragraphs 4.02 and 4.06

SECTION III. FEE-BASIS AND CONTRACT DIALYSIS IN NON-VA DIALYSIS FACILITIES

4.06 VA SUPPORT FOR DIALYSIS CARE PROVIDED IN NON-VA FACILITIES

a. General Policy. Subject to eligibility limits on non-VA provided care, if the required dialysis care cannot be provided directly to a VA patient (such as if the patient lives too far from the VA dialysis unit to return for treatments, or the VA dialysis unit is overtaxed) or by another Federal Government facility under contract with VA, treatments may be provided in non-VA facilities, such as fee-basis or contract dialysis, or by using VA equipment placed in a non-VA hospital by means of a revokable license.

b. Conditions for Provision of Contract/Fee-Basis Dialysis. Fee-basis or contract dialysis for a patient on OPT/NSC status without any other special eligibility for outpatient care supported by VA will not be authorized until full consideration has been given to other possibilities of financial support, such as Medicare and other third-party payers. Where such resources are adequate the NSC patient will be discharged to continue care in a non-VA unit not at VA expense. Only if it is determined by the facility staff that resources such as Medicare would be clearly insufficient should approval of fee-basis or contract dialysis care for a veteran who is otherwise eligible for non-VA care be made by the Director of a VA facility with a designated dialysis program. Any NSC patient placed on contract/fee basis dialysis should be reevaluated periodically to determine eligibility (if the patient has become eligible) for other modes of support (such as Medicare) which may permit discharge from the VA program. A 1-year limitation is placed on OPT/NSC care unless an extension is authorized. If continued VA OPT/NSC care is considered necessary, it may be recommended by the attending physician and approved by those physicians at the individual VA medical center authorized to approve continued OPT/NSC care. Hospitalization of OPT/NSC patients in non-VA facilities (such as for treatment of serious complications during contract dialysis) ordinarily cannot be authorized and paid for by VA. VA patients or potential patients on contract or fee dialysis should be informed of such limitations. No person will be admitted to a VA medical center for the sole purpose of placement on OPT/NSC treatment.

c. Limitations on Authority for VA Medical Centers Without Dialysis Programs to Authorize Contract or Fee Dialysis. VA medical centers without a dialysis program will not independently authorize fee-basis or contract dialysis care despite clinic of jurisdiction or similar authority, except in connection with ongoing contract hospitalization or in order to provide authorized emergent medical care to veterans eligible for such contract care under provisions of 38 U.S.C. 603. Individuals inquiring about care in the VA dialysis program will be informed of the limitation on VA payment for care in non-VA facilities (see subpar. (b)) and will be referred to the closest VA dialysis program for evaluation of administrative eligibility using established criteria and priorities and medical assessment. The VA facility closest to the patient's home or the clinic of jurisdiction may carry out administrative aspects of contract or fee-basis dialysis after such treatment is authorized by the Director of a VA medical center with a dialysis program.

d. Payment and Budgeting Consideration. See paragraph 4.09.

SECTION IV. NONVETERANS RECEIVING ESRD SERVICES AS MEDICARE BENEFICIARIES

4.07 (RESERVED.)

SECTION V. REPORTING

4.08 REPORTING

a. "AMIS" Report. (Segment J-19. 8JD2, RCS10-0049) Each VA facility with an authorized chronic dialysis program and/or supporting patients on contract/fee-basis dialysis will submit the appropriate AMIS report quarterly summarizing the dialysis program activity for the report period. Care must be taken to avoid "double-counting" or other duplicate reporting of the same patients cared for in several VA programs (e.g., a center and its satellite).

b. VA has agreed to participate in the USRDS (United States Renal Data System) being developed for NIH with the cooperation of HCFA. ESRD patient information should be submitted in accordance with instructions.

SECTION VI. BUDGET

4.09 BUDGETING CONSIDERATIONS

When fee-basis or contract dialysis is utilized, VA payment will ordinarilly be limited to the amount that Medicare has authorized that facility to receive for providing the same service to Medicare beneficiáries. VA may pay 100 percent of the approved charge while Medicare may deduct coinsurance and deductible amounts.

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CHAPTER 5. OUTPATIENT OXYGEN THERAPY

5.01 SCIENTIFIC BACKGROUND

a. The use of oxygen therapy in the home on a long-term basis is common practice and can benefit patients with chronic hypoxemia while decreasing their medical care costs.

b. Complications of hypoxemia usually occur below an arterial oxygen tension of 55 mm Hg. A number of beneficial effects of long-term oxygen therapy have been clearly documented: reduction in pulmonary arterial pressure and polycythemia, improvement in neuropsychologic performance, increase in exercise tolerance, and reduction in the number of hospitalizations, as well as improvement of the quality of life. It has also been suggested that the long-term prognosis in patients with cor pulmonale is improved by long-term oxygen therapy. Oxygen is usually effective when delivered at rates between 1 and 4 liters per minute.

c. Patients may develop marked hypoxemia during exercise or sleep only. Oxygen supplements during sleep and exercise may be helpful to people who have hypoxemia only during these activities.

5.02 POTENTIAL PROBLEMS IN OUTPATIENT OXYGEN THERAPY

a. Patients who have hypercapnia (elevated PaC02) may develop further alveolar hypoventilation as the hypoxic stimulus to respiration is reduced with supplemental oxygen. In these patients, it is advisable to monitor the effect of oxygen with serial arterial blood gases to demonstrate no significant adverse effects.

b. The effectiveness of oxygen therapy may be reduced and associated risks are increased in patients who continue to smoke. Thus, careful evaluation of the risk/benefit ratio should be done before starting or renewing oxygen therapy for smokers.

5.03 PATIENT SELECTION AND CLINICAL INDICATIONS

a. The patient should be on optimal drug therapy as determined by a physician knowledgeable in the treatment of chest diseases. Smoking cessation should be strongly recommended.

b. Documentation of one or more of the following indications for chronic oxygen supplementation should exist before oxygen is prescribed:

(1) Resting arterial oxygen tension (Pa02) below 55 mm Hg while the patient is breathing room air, in a stable clinical state.

(2) Desaturation by oximetry with a saturation below 88 percent at rest. Supplemental oxygen would be required during exercise or sleep if desaturization to below 88 percent occurs during exercise or during sleep.

(3) Resting arterial oxygen tension (Pa02) of 60 mm Hs or less with hypoxic organ dysfunction such as cor pulmonale, or polycythemia.

5.04 MODE AND DURATION OF THERAPY

Most patients show an acceptable improvement of arterial oxygen tension on oxygen at 1 to 4 liters per minute. A few patients, particularly those with restrictive lung disorders,

may require higher flow rates (e.g., 5 to 8 liters per minute). In these patients, the need for higher oxygen flow rates should be documented by an arterial blood gas analysis with the patient receiving oxygen. The duration of treatment will vary with the clinical manifestations of chronic hypoxemia and demonstrations of achievement of PaO2 of between 55 and 90.

5:05 TYPES OF OXYGEN EQUIPMENT AND SERVICES

The physician responsible for the respiratory care program should be familiar with both the medical and economic aspects of the various methods of delivery. When low flow oxygen is prescribed, it is usually more economical to use an oxygen concentrator, or the use of certain fixed flow gauges may prevent waste through unnecessarily high flow rate when bottled oxygen is used. Oxygen conserving cannulae, pulse dose delivery devices and transtracheal catheters are reported to reduce the oxygen consumed by 50 to 75 percent and may be particularly useful with portable systems. It has been demonstrated in several locations that the purchase of concentrators is more economical than rental contracts.

5.06 PERIODIC REVIEW

These patients should be clinically and physiologically reevaluated and the need for oxygen therapy documented every 6 months for the first year. Thereafter, the need for continuing oxygen must be documented on at least a yearly basis in conjunction with the patient's regular medical evaluation.

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CHAPTER 6. INFECTIOUS DISEASES

6.01 GENERAL CONSIDERATIONS

The treatment, control and prevention of infectious diseases in all VA health care facilities require programs which are similar.

6.02 THE ADVISORY COMMITTEE ON INFECTIOUS DISEASES

a. A Central Office Advisory Committee on Infectious Diseases exists to advise the ACMD (Assistant Chief Medical Director) for Clinical Affairs on policy. The Director, Medical Service, acts as liaison through the Program Director in Infectious Diseases. The committee ordinarily consists of the Infectious Disease Field Advisory Group (Medical Service) under the direction of the Program Director in Infectious Diseases, who is specially trained in this medical subspecialty.

b. The committee should meet at least once each year, however, it may meet more frequently if necessary. Examples of topics of concern to this group might be: Identification and management of epidemic diseases, immunization programs, the use of anti-infectious agents, and the coordination of programs to control resistance to the toxicity of antimicrobials. Subcommittees may be required to consider such aspects as: Surveillance methods, training of infection control personnel, clinical microbiology laboratories, regional VA diagnostic facilities, antifiotic usage, and adverse reactions to antimicrobial agents.

c. Some of the areas in which the committee might make recommendations include:

(1) Work force,

(2) Design of health care and extended care facilities, including the Microbiology Laboratory,

(3) Policies on prevention and control of communicable diseases,

(4) Policies on the use and abuse of antimicrobials and anti-infectious biologics,

(5) Training recommendations,

(6) Policies for methods of infection surveillance and data analysis,

(7) Advice on the development and adoption of new laboratory procedures,

(8) Development of specialized resources within selected Laboratory Services, and,

(9) AIDS (in conjunction with the AIDS Program Office).

6.03 HOSPITAL INFECTION CONTROL COMMITTEE

Each health care facility should establish an Infection Control Committee. (See M-1, pt. I, ch. 26, par. 26.07h). A physician, specially trained in Infectious Diseases, should be chairperson of this committee. The Hospital Infection Control Committee may serve as a consultant to the Safety, Occupational Health and Fire Protection Committee on matters relevant to infection control.

6.04 INFECTIOUS DISEASE SECTIONS

Infectious Disease Sections under the Medical Service should be formed as a subspecialty at all health care facilities where feasible. The functions of such a section should include the following:

a. Provide optimal patient care with relation to infectious diseases by consultation throughout the facility. This would include the consideration of inpatient and outpatient problems.

b. Conduct the business of the Infection Control Committee, including policy recommendations in such areas as:

(1) Procedures for isolation and prevention of infection,

(2) Environmental sanitation,

(3) Infection surveillance,

(4) Epidemiologic studies,

(5) Employee health (where infection is involved), and,

(6) Immunization programs.

c. Advise appropriate local facility committees regarding:

(1) Selection and control (restriction) of antimicrobials,

(2) Audit of antimicrobial usage, and,

(3) The purchase of chemical supplies and equipment related to infection control in the facility.

d. The Chief, Infectious Disease Section, or a designee should have close liaison with Laboratory Service and work actively with the Chief, Laboratory Service, on the development and implementation of programs and policies in the Microbiology Section of the Laboratory Service, particularly with regard to staffing, space and equipment. The Chief, Infectious Disease Section, should consult with appropriate members of the Laboratory Service regarding the collection of specimens, the establishment of priorities for collection of specimens, the establishment of priorities for cultures, susceptibility tests, new diagnostic procedures, and the compilation of laboratory data for epidemiologic evaluation.

e. The Section Chief should work with the Associate Chief of Staff for Education or appropriate staff of other services to maintain a program of inservice education. This program should assist in providing improved knowledge of infectious diseases to appropriate medical center personnel.

f. The Section Chief should maintain a liaison function with other local hospitals and public health authorities in the community regarding infectious disease problems.

6.05 STAFFING GUIDELINES

a. Suggestions for staffing of Infectious Disease Sections should include the following:

(1) A physician section chief.

(2) One staff physician, in addition, for each 200-250 GM&S (general medical and surgical) beds and one per 500 all other beds. In areas of high incidence of AIDS, this number will need to be increased.

(3) At least one full-time practitioner of infectious disease control with the same distribution as staff physicians as in subparagraph (2) above, where possible. In areas of high incidence of AIDS, this number will need to be increased.

(4) Subspecialty resident positions in Infectious Diseases where appropriate. Specific infectious diseases training positions in AIDS may be of value as necessary.

(5) One unit secretary and clerk-typist or more as necessary. This is critical to the functioning of the Section.

b. Suggestions for Associated Services

The Laboratory Service should have skilled (Ph.D. level or equivalent) leadership in the Microbiology Section and be staffed adequately to ensure provision of necessary services.

6.06 EQUIPMENT AND SERVICE

The health care facility should furnish whatever space, equipment, office supplies and other clerical services necessary for the effective operation of the section. This should include appropriate data processing equipment (or access to such items) to fullfill the mission of the section as well as adequate funds for continuing education for infection control personnel.

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CHAPTER 7. SICKLE CELL SCREENING AND COUNSELING PROGRAM

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CHAPTER 7. SICKLE CELL SCREENING AND COUNSELING PROGRAM

SECTION I. GENERAL

7.01 POLICY

a. Title 38, United States Code, sections 651-654, authorizes a Sickle Cell Anemia program within VA. The specific provisions of this authority are:

(1) Screening, counseling and medical treatment of eligible sickle cell anemia patients. (See par. 7.05)

(2) Research and research training in diagnosis, treatment and control of sickle cell anemia based on the screening examinations and treatment.

(3) Participation by the patient will be voluntary.

(4) Information and records of the patient will be maintained in accordance with the confidentiality requirements of 38 U.S.C., section 4132. See VHS&RA manual M-1, part I, chapter 9.

(5) Annual report of the administration of this program, including recommendations for additional legislation which may be deemed necessary.

b. The Chief Hematologist at the facility having a VA Sickle Cell Screening and Counseling program has overall responsibility for administration of the program.

7.02 OBJECTIVES

a. To provide a voluntary screening program for all patients who are recognizable as risks for Hb (hemoglobin) S and/or G-6-PD (glucose-6-phosphate dehydrogenase) deficiency who are admitted to the hospital or who are eligible for treatment in the outpatient clinic.

b. To provide a voluntary educational program on the basic medical and genetic aspects of the hemoglobinopathies and enzyme deficiency to all such patients and their spouses.

c. To educate physicians, nurses and other VA personnel about sickle cell disorders and G-6-PD deficiency.

SECTION II. PROCEDURES

7.03 PATIENT SELECTION

Persons otherwise eligible for VA bed care or outpatient treatment are potential candidates for participation in the Sickle Cell program. See 38 CFR Section 17.135. Where applicable and medically indicated, spouses of patients may participate in the program but actual treatment is limited to eligible veterans. Preliminary screening of persons for identification of potential candidates will be performed in the admissions office. A patient's racial background or ethnic orgin will be ascertained and placed in lower right corner of item 1 of VA Form 10-10m, Medical Certificate and History. For uniformity of data analysis, race or ethnic origin and codes for race contained in coding instructions in MP-6, part XVI, Supplement No. 1.1, for the Patient Treatment File

program will be used. A rubber stamp or other suitable means similar to the following will be used for designating the appropriate race of the applicant:

Race or Ethnic Origin of Applicant

(1) Spanish American-White
(2) Spanish American-Black
(3) American Indian (Includes Aleutians and Eskimos)
(4) Black
(5) Asian
(6) White
(7) Other

7.04 PATIENT CONSENT

Except for preliminary screening in the admission office, participation in the Sickle Cell program by the applicant will be voluntary and will not be a prerequisite for any other VA benefit. An SF 522 will be used to obtain the applicant's written consent. Item A1 of the form will include the statement "Participation in Sickle Cell Screening and Counseling Program." Item B1 of the form will include the statement "Necessary laboratory examination(s) for hemoglobinopathies." All other applicable items on the form will be completed.

7.05 DRAWING BLOOD SAMPLES

Blood samples for testing will be obtained, if available, from the clinical laboratory using the residue of blood that has been obtained for routine blood counts or other ordered laboratory tests when possible.

7.06 LABORATORY METHODOLOGY

Laboratory Methodology

a. Hemoglobin Electrophoresis. A number of accurate techniques are available for determining the hemoglobin type present. Among the preferred methods are electrophoresis at alkaline pH on cellulose acetate membranes, isoelectric focusing, minicolumn chromatography, and high performance liquid chromatography. Any of these techniques are suitable for detecting the presence of hemoglobin S and most other common abnormal hemoglobins. Testing should be done in a CAP approved laboratory. To verify the presence of hemoglobin S, solubility tests should be performed. Techniques that can be applied for the confirmation of abnormal hemoglobins are citrate agar electrophoresis at pH 6.1, isoelectric focusing, and globin chain electrophoresis. The Reference Laboratory for the program is located at the VA Medical Center, Jackson, MS, and is available for questionable results and difficult problems.

b. Glucose-6-phosphate dehydrogenase. The fluorescent spot test will be used to detect the presence or absence of G-6-PD deficiency. The reference laboratory at the VA Medical Center, Jackson, MS, is available for questionable results.

7.07 REPORTING RESULTS ON SICKLE CELL DISEASE

Results of all tests are recorded on a laboratory form and filed in the patient's medical record. The laboratory will maintain a log identifying each patient by name, number, hospital location, and results. These data are used in the compilation of monthly records, the annual report, and for quality assurance and inspection reports. All persons tested will be given an ID card, VA Form 10-1450, that indicates the results of the tests.

7.08 EDUCATIONAL SESSIONS

a. The hematologist will determine the best technique for the method of conducting educational programs for patients, their spouses and hospital personnel. One of the effective methods is to hold daily or tri-weekly sessions of all patients (screened or otherwise) conducted by the counselor, utilizing such modalities as brochures, film strips, movies and lantern slides with appropriate narration. A question and answer period can be instituted following the formal session. A patient with a hemoglobin disorder or G-6-PD deficiency should be given the opportunity to attend a private counseling session, preferably with spouse (who may be tested voluntarily) so that genetic as well as medical aspects of the findings may be discussed. With the patient's written permission, tape recordings of these sessions may be made and the discussions later reviewed by the counselor with the hematologist for suggestions and/or recommendations about counseling techniques and medical information. Training of counselors will be the responsibility of each participating hospital.

b. If possible, educational exhibits describing sickle cell disorders may be constructed and placed in the lobby of the medical facility, with educational brochures, to make this information available and act as a reminder for personnel and visitors. Availability of nearby sickle cell centers for non-VA beneficiaries can be disseminated through such exhibits.

7.09 STAFFING

a. In a hospital that is able to screen one thousand new patients per year, one medical technician, grade GS 5-7, and one counselor, grade 7-9, can effectively handle the program. If a hospital were able to screen only half this amount, a single FTEE capable of both counseling and the laboratory support work would be required.

b. The position of counselor requires a practical understanding of the methods and techniques used in interviewing and counseling. The counselor will have the ability to communicate effectively with black veterans and their spouses and with persons from other population groups who may be tested with respect to the highly sensitive area of sickle cell disorders. Also required is the ability to develop sufficient knowledge of the medical and genetic aspects of the significance and implications of these problems. Imagination and skill in adapting and creating teaching aids and information materials are requisite. A prototype job description for a GS-7 counselor is available from the Central Office Personnel Service. A 1-week course or apprenticeship in counseling techniques is desirable before initiating the program. There are numerous centers and considerable resource materials available for training in counseling and introduction of educational concepts.

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CHAPTER 8. ALLERGEN THERAPY

8.01 EXTRACTS AND VACCINES

a. Source. Allergen extracts for testing and therapy are supplied to qualified centers by a centralized Department of Veterans Affairs program in cooperation with U.S. Army, WRAMC (Walter Reed Army Medical Center) thru USACAEL (U.S. Army Centralized Allergen Extracts Laboratory).

b. Administration. The program is administered by the Director of VALMC (VA Allergy), at VA Medical Center, Chicago (Lakeside), IL, in consultation with the VA Allergy Advisory Group.

c. Requests. All requests for allergen diagnostic or treatment extracts must come to the Director of VALMC. Only VA centers serviced by a Board Certified Allergist (or equivalent credentials as determined by the Director of Allergy) will be eligible for this program. All requests will be in a standard format as set out by VA and USACAEL.

8.02 SELF-ADMINISTRATION OF IMMUNOTHERAPY

a. Under past policy, self-administration of allergenic material was permitted in exceptional cases.

b. New policy dictates that under no circumstances will these potent extracts from VA/USACAEL be self-administered by the veteran patient. All allergen testing and treatment must be given by trained personnel in a setting where there is access to adequate measures to treat an anaphylactic reaction.

c. The certified allergist prescribing IT (immunotherapy) is responsible to ensure that the personnel administering IT in a VA medical center, VA outpatient clinic, or other outside setting are adequately versed in this type of therapy and the treatment of the rare adverse reactions that occur.

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